BIOSITE®

NEW DIMENSIONS IN DIAGNOSIS™

510(k) Summary

510(k) number: __K093032_____

NOV 13 2009

Date Prepared: 03 November 2009

Submitter:	Biosite, Inc.	**Contact:**	Mara Caler
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Trade (proprietary) name:	**Common Name (Device Type):**
Triage® Total 3 Controls and Triage® Total 3 Calibration Verification Set	Assayed Quality Control materials

Class:	1
Regulation number:	21 CFR 862.1660
Product Code:	JJY
Panel:	Clinical Chemistry

Predicate devices:
K072892: Triage® Total 5 Controls and Calibration Verification Set

The Triage® Total 3 Controls and Triage® Total 3 Calibration Verification Set is substantially equivalent to other products in commercial distribution intended for similar use, with substantial equivalency to the currently marketed Triage® Total 5 Controls and Triage® Total 5 Calibration Verification Set

Device Description:
The Triage® Total 3 Controls and the Triage® Total 3 Calibration Verification Set are quality control materials that contain CKMB, cardiac troponin I, and BNP at multiple concentrations. These materials are used to assist the laboratory in monitoring test performance throughout the measurable range. They are not calibrators and are not used to calibrate the Triage® tests. The results of quality control testing do not impact direct patient care and should not influence clinical decision making process the physician uses to make clinical diagnosis for the patient.

Intended Use / Indications for Use:
The Triage® Total 3 Controls are assayed controls to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance.

The Triage® Total 3 Calibration Verification are assayed materials to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance.

Summary of Changes from Predicate Device:
The predicate device is the Triage® Total 5 controls and Triage® Total 5 Calibration Verification Set. The changes from the predicate device are:

- Lower levels of analyte
- Removing the d-dimer analyte and the myoglobin analyte from the controls

Substantial Equivalence to Predicate Device:
The predicate device is the Triage® Total 5 Controls and Triage® Total 5 Calibration Verification Set.

- The proposed Triage® Total 3 Controls and Triage® Total 3 Calibration Verification Set are substantially equivalent to Triage® Total 5 Controls and Total 5 Calibration Verification Set in intended use, technology and performance.
- Bench performance testing was performed comparing the new device and the predicate device, and was found to be substantially equivalent.

List of Similarities:

- Intended use is unchanged (except for the removal of the d-dimer analyte and the myoglobin analyte from the control set)
- Indications for use is unchanged
- The operating principle is unchanged
- The technology is unchanged
- The analytical performance is unchanged or improved

List of Differences:

- Control level 1 contains a lower level of troponin I than the predicate device
- The individual assays contained within the control material has been reconfigured (myoglobin and d-dimer have been removed from the control set).

Comparison Table:

Characteristic	**Predicate:** K072892: Triage® Total 5 Controls and Calibration Verification Set	Triage® Total 3 Controls and Calibration Verification Set
Intended use	The Triage® Total 5 Controls are assayed controls to be used with the Triage® BNP Test, Triage® CardioProfilER Panel, Triage® Cardiac Panel and Triage® S.O.B Panel devices and the Triage® Meter to assist the end user in monitoring product performance. The Triage® Total 3 Calibration Verification are assayed materials to be used with the Triage® BNP Test, Triage® CardioProfilER Panel, Triage® Cardiac Panel and Triage® S.O.B Panel devices and the Triage® Meter to assist the end user in monitoring product performance.	The Triage® Total 3 Controls are assayed controls to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance. The Triage® Total 3 Calibration Verification are assayed materials to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance.
Levels	2	2 (same)
Format	Liquid/frozen	Liquid/frozen (same)
Handling	Thaw, no other user manipulation required	Thaw, no other user manipulation required (same)
Stability	8 months	4 weeks (real time stability on-going)
Matrix	Human EDTA plasma	Human EDTA plasma (same)

Performance Characteristics:
The Triage® Total 3 Controls and Cal Verification set were evaluated for value assignment and stability.

Conclusion:
Performance testing demonstrates that the Triage® Total 3 Control and Triage® Total 3 Calibration Verification Set are as safe, as effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Biosite Incorporated
c/o Mara Caler
9975 Summers Ridge Road
San Diego, California 92121

NOV 13 2009

Re: k093032
Trade Name: Triage® Total 3 Controls and Triage® Total 3 Calibration Verification Set
Regulation Number: 21 CFR §862.1660
Regulation Name: Assayed Quality Control Materials
Regulatory Class: Class I
Product Codes: JJY
Dated: September 25, 2009
Received: September 29, 2009

Dear Ms. Caler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K093032

Device Name: Triage® Total 3 Controls and Triage® Total 3 Calibration Verification Set

Indications for Use:

The Triage® Total 3 Controls are assayed materials to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance.

The Triage® Total 3 Calibration Verification Set are assayed materials to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance.

Prescription Use __X_____	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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